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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/541,297 | 06/30/2005 | Jurgen Kress | | 6636 |

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EDWIN D. SCHINDLER
4 HIGH OAKS COURT
P.O. BOX 4259
HUNTINGTON, NY 11743-0777

| EXAMINER | |
|---|---|
| NIA, ALIREZA | |

| ART UNIT | PAPER NUMBER |
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| 3779 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/541,297 | KRESS, JURGEN | |
| | Examiner | Art Unit | |
| | ALIREZA NIA | 3779 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *29,30 and 32-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,30 and 32-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

1. The amendment to claims 29, 47, 48 and the cancellation of claim 31 in the response filed on October 12th, 2010 is acknowledged.

2. Claims 29-30 and 32-48 remain pending in the application.

### *Response to Arguments*

3. Applicant's arguments with respect to claims 29-48 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 29-30 and 32-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 29 recites the limitation "said working channel" in line 5. There is insufficient antecedent basis for this limitation in the claim.

### *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**8. Claims 29-30, 32-38, 42, and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein 4,646,722 in view of Vescovo, Jr. (herein Vescovo) 4,972,825.**

9. Regarding claims 29-30, 32-38, and 42, Silverstein discloses an endoscope 8 with hygiene protection 10,30, comprising a cover 10,30,48 closed at a distal end 32 and transmissible for optical information via 32,44,46, at least on a front face 32 of said cover 10,30,48, and capable of being rolled via 48 in an axial direction of said endoscope 8, wherein said cover 10,30,48 includes a material 48 that is airtight, watertight and impermeable to pathological microorganisms with connection of said cover 10,30,48 to said working channel 36,38 to said distal end 32 of said cover 10,30,48 being made airtight, watertight and impermeable to pathological microorganisms (col. 6, lines 35-46), a working channel 38,36 extending parallel to said endoscope 8 via 21 and terminating in an open mode via 38,40,42 at said distal end 32 of said cover 10,30, said working channel 36,38 being connected only to said distal end 32 of said cover 10,30,48 and positioned between an outer side 12 of said endoscope 8 via 21 and an inside of said cover 10,30,48 (col. 6, lines 16-46, 58-68, col. 7, lines 1-14, 41-54, figs. 1-3), and consisting of only a single vacuum channel 64 (figs. 5-6, col. 7, lines 60-65), having at least one opening A, and terminating at said inside of said cover 10,30,48 with said at least one opening A terminating inside of said cover 10,30,48 in a direction facing said endoscope 8 (the direction is facing endoscope 8 and portion 14 of endoscope 8), said single vacuum channel 64 being a dedicated channel 64 that is a different channel 64 from said working channel 36,38 (fig. 4). Silverstein further discloses means 48 (the elastomeric material) for varying cross-sectional diameter via 48,60,64 (col. 7, lines 47-60), wherein said cover 10,30,48 is flexible and elastic and foldable in the axial direction of said endoscope 12 via 48 (col. 6, lines 58-68), wherein at

least a portion of said cover 10,30,48 inherently has an internal diameter that is larger than an external diameter 12 of the endoscope 8. Silverstein further discloses a transparent pane or lens 32,44,46 on said distal end 32 of said cover 10,30,48 on said front face 32 of said cover 10,30 (col. 6, lines 47-57), wherein said transparent pane or said lens 32,44 at least partially forms said front of face 32 of said distal end 32 of said cover 10,30,48 via 46, wherein said distal end 32 of said cover is an optically transparent cap via 32,44, wherein said distal end 30,32 of said cover 10,30,48 has a wall thickness that is greater than wall thickness of a non-distal region 48 of said cover 10,30,48, wherein said cover 10,30,48, when open at a proximal end 48, is fixable to be airtight on a shaft 12,14 of said endoscope 8 via 48,66 (col. 6, lines 62-68). Silverstein further discloses means (suction, fig. 4) for applying sub-atmospheric pressure to said single vacuum channel 64 during use of said endoscope 8 (col. 6, lines 28-35). Silverstein further discloses depressions 21 in an axial direction on an outer surface of said endoscope 8 (col. 6, lines 16-21).

10. However, Silverman fails to positively disclose the single vacuum channel, having at least one opening and terminating at said inside of said cover with said at least one opening terminating inside of said cover in a direction facing said endoscope for pressing said cover onto said endoscope via application of sub-atmospheric pressure.

11. Vescovo teaches a single vacuum channel 33, having at least one opening (fig. 4), and terminating at an inside 15 of a similar cover 11,13 with said at least one opening terminating inside 15 of said cover 11,13 in a direction facing an analogous endoscope L for pressing said cover 11,13 onto said endoscope L via application of sub-atmospheric pressure via C,37,39 (fig. 4, col. 2, lines 4-62), providing an improved endoscope with hygiene protection having an improved single vacuum channel that is capable of efficiently removing air from an interior of

the cover via a source of sub-atmospheric pressure in order to allow the cover to collapse about the endoscope to maintain sterility and sanitation of the endoscope while allowing easy maneuvering of the endoscope by the user (col. 2, lines 39-62).

12. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the single vacuum channel 64 and the cover 10,30,48 of Silverman with the single vacuum channel 33 and its connection with the cover 11,13 as taught by Vescovo in order to have provided an improved endoscope with hygiene protection having an improved single vacuum channel that is capable of efficiently removing air from an interior of the cover via a source of sub-atmospheric pressure in order to allow the cover to collapse about the endoscope to maintain sterility and sanitation of the endoscope while allowing easy maneuvering of the endoscope by the user during surgery.

13. With respect to claims 47-48, Silverstein discloses attaching a hygiene protection 10,30 to an endoscope 8, said endoscope 8 including a cover 10,30,48 closed at a distal end 32 and transmissible for optical information via window 32,44, at least on a front face 32 of said cover 10,30,48, and capable of being rolled via 48 in an axial direction of said endoscope 8, a working channel 36,38,39 extending parallel to said endoscope 8 via 21 and terminating in an open mode 42 via 40 at a distal end 32 of said cover 10,30,48, said at least one working channel 36,38,39 being connected only to said distal end 32 of said cover 10,30,48 and positioned between an outer side 12 of said endoscope 8 via 21 and an inside of said cover 10,30,48, and consisting of only a single vacuum channel 64, having at least one opening A (see inserted image 1 below), and terminating via A at said inside of said cover 10,30,48 via 48 in a direction facing said endoscope 8 via 14 (the direction is facing endoscope 8 and portion 14 of endoscope 8), said

single vacuum channel 64 being a dedicated vacuum channel 64 that is a different channel from said working channel 36,38 (col. 6, lines 30-46, fig. 3), said method comprising the steps of coating an inner side of said window 32,44 at said distal end 32 of said cover 10,30 for producing optical contact between said window 32,44 and an optical channel of said endoscope (col. 6, lines 52-57), introducing a distal end of said endoscope 8 into said cover 10,30,48, said cover being open at a proximal end 48 and closed at said distal end 32 thereof, rolling said cover 48 onto, or unfolding said cover 48 with, an enclosure 12 of said endoscope 8 and said working channel 36,38 via 21, and applying a sub-atmospheric pressure via (suction, see fig. 5-6, col. 7, lines 60-65) to said single vacuum channel 64, fixing said working channel 36,38 at said distal end 32 of said cover 10,30,48 via 40,42, said working channel 36,38 being positioned in depressions 21 provided on an outer surface 12 of said endoscope 8 and said working channel 36,38 via 35.

14. However, Silverman fails to positively disclose the step of applying sub-atmospheric pressure to said single vacuum channel is for pressing said cover onto said endoscope.

15. Vescovo teaches a similar single vacuum channel 33, having at least one opening (fig. 4), and terminating at an inside 15 of a similar cover 11,13 with said at least one opening terminating inside 15 of said cover 11,13 in a direction facing an analogous endoscope L, wherein Vescovo teaches a method of attaching a hygiene protection system to the endoscope by applying sub-atmospheric pressure via C,37,39 to said single vacuum channel 33 for pressing said cover 11,13 onto said endoscope L (fig. 4, col. 2, lines 4-62), providing an improved method of attaching a hygiene protection system to an endoscope having an improved single vacuum channel that is capable of efficiently removing air from an interior of the cover via a source of

sub-atmospheric pressure in order to allow the cover to collapse about the endoscope to maintain sterility and sanitation of the endoscope while allowing easy maneuvering of the endoscope by the user (col. 2, lines 39-62).

16. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the single vacuum channel 64 and the cover 10,30,48 of Silverman with the single vacuum channel 33 and its connection with the cover 11,13 as taught by Vescovo in order to have provided an improved method of attaching a hygiene protection system to an endoscope having an improved single vacuum channel that is capable of efficiently removing air from an interior of the cover via a source of sub-atmospheric pressure in order to allow the cover to collapse about the endoscope to maintain sterility and sanitation of the endoscope while allowing easy maneuvering of the endoscope by the user during surgery.

**17. Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein 4,646,722 in view of Vescovo, Jr. (herein Vescovo) 4,972,825 further in view of Kuramoto 5,630,795.**

18. Silverstein in view of Vescovo discloses the invention as discussed above. Silverstein further discloses an endoscope 8 with hygiene protection 10,30,48, comprising a cover 10,30,48 closed at a distal end 32 and transmissible for optical information via 32,44, at least on a front face 32 of said cover 10,30,48, and capable of being rolled via 48 in an axial direction of said endoscope 8, a working channel 35 extending parallel to said endoscope 8 and terminating in an open mode via 36,42 at said distal end 32 of said cover 10,30,48, said working channel 35 being connected only to said distal end 32 of said cover 10,30,48 and positioned between an outer side 12 of said endoscope 8 and an inside of said cover 10,30,48 via 21 (col. 6, lines 16-46, col. 6,

lines 58-68, col. 1-14, col. 7, lines 41-54, figs. 1-3). Silverstein further discloses depressions 21 in an axial direction on an outer surface of said endoscope 8, said depression corresponding in shape and in depth to a diameter and profile of said working channel 35,38 (col. 6, lines 16-21).

19. However, Silverstein in view of Vescovo fails to positively disclose said depressions correspond in shape and in depth to a diameter and profile of said vacuum channel, wherein said depressions have a width, running in the axial direction on said outer surface of said endoscope.

20. Kuramoto teaches a vacuum channel 122,344, having at least one opening 125 with said at least one opening 125 terminating in a direction facing said endoscope 101,113, said vacuum channel 122,344,361,362 being a single dedicated vacuum channel that is a different channel from any other working channel (col. 6, lines 14-35, col. 7, lines 20-67, col. 12, lines 29-53, 63-67, col. 13, lines 1-13, col. 25, lines 37-64, figs. 17,44a,44b45a,45b) in use with an analogous endoscope with hygiene protection. Kuramoto further teaches depressions 352,367 corresponding in shape and in depth to a diameter and profile of said vacuum channel 344,361,362, wherein said depressions 352,367 have a width, running in the axial direction on said outer surface of said endoscope 351,365 which is smaller than the width of said depressions 352,367 at their center points (figs. 44a,b,45a,45b), making it possible to not only clean the forward-end portion of the endoscope to ensure disinfection but also allowing to reduce the diameter of the inserting section of the endoscope (col. 25, lines 55-64).

21. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the endoscope with hygiene protection of Silverstein in view of Vescovo with the above discussed limitations as taught by Kuramoto in order to have provided an improved endoscope with hygiene protection that has an endoscope having a narrow inserting section that

makes it possible to comfortably clean the forward-end portion of the endoscope to ensure disinfection of the endoscope distal tip while inside of said cover by providing ample space for maneuverability between the endoscope inserting section and the inside of the hygiene protection cover.

22. With respect to the recitation "vacuum channel, having at least one opening, and terminating at said inside of said cover" in claim 29, it would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that based on the above discussed modification of the Silverstein in view of Vescovo in view of Kuramoto that the vacuum channel 122,344,361 with at least one opening 125, would have terminated inside of said cover with said at least one opening 125 terminating inside of said cover 10,30,48 in a direction facing said endoscope 101,113 to clean the forward-end portion of the endoscope to ensure disinfection of the endoscope distal tip while inside of said cover, wherein said vacuum channel 122,344,361 would also have been detachable from said distal end of said cover 10,30 since 122,344,361 is removable.

23. Regarding the recitation "said working channel…detachably connected to said distal end of said cover" in claim 45, it would have also been obvious to one ordinary skill in the art at the time of the invention to have removed working channel 35 via 40,42 in order to facilitate simple replacement of damaged working channels, since separation of elements, where removability would be desirable, is a design consideration within the skill of the art.

**24. Claims 41 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein 4,646,722 in view of Vescovo, Jr. (herein Vescovo) 4,972,825 further in view of Sidall 4,741,326.**

25. Silverman in view of Vescovo discloses the invention as discussed above. Although Vescovo further discloses the single vacuum channel 33,C,39 is capable of extending for at least a portion of a length of the cover 11,13 via 39, Silverman in view of Vescovo fails to positively disclose said working channel and said single vacuum channel are fixed to said distal end of said cover.

26. Sidall teaches a single vacuum channel 5 that extends for at least a portion of a length of said cover 1 (fig. 5), and wherein said working channel 19 and said single vacuum channel 5 are fixed to said distal end 3 of said cover 1 (fig. 5) such that the channels 5,19 are positioned such that they remain outside of the endoscope shaft while remaining within the confines of the cover (col. 3, lines 56-65).

27. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the cover of Silverman in view of Vescovo with the above discussed limitations as taught by Sidall in order to have provided an improved cover having improved vacuum and working channels such that the channels are positioned such that they remain outside of the endoscope shaft while remaining within the confines of the cover.

**28. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein 4,646,722 in view of Vescovo, Jr. (herein Vescovo) 4,972,825 further in view of Adair 5,433,221.**

29. Silverstein in view of Vescovo discloses the invention as discussed above.

30. However, Silverstein in view of Vescovo fails to positively disclose the cover to be conically enlarged in a vicinity of said proximal end with a portion of said cover being folded

backwardly to be wrinkle-free in said vicinity of said proximal end and fixable via a chemically inert and non-toxic adhesive.

31. Adair teaches an analogous cover 10 used in covering an endoscopic surgical camera, the cover 10 having conically enlarged in a vicinity of its proximal end 12 (the distal end 14 having a smaller diameter than proximal end 12, col. 4, lines 33-42). The cover also having a portion 20 that is folded backwardly (col. 4, lines 55-59) wherein the proximal end 12 is fixable via an adhesive 18 (col. 4, lines 50-53) resulting in an improved sterile cover for an unsterile endoscope enhancing operating room procedures.

32. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the device of Silverstein in view of Vescovo with above discussed limitations as taught by Adair in order to have an improved sterile cover for an unsterile endoscope enhancing operating room procedures by minimizing sterility problems with an apparatus of this type that requires a minimal amount of handling to be put in use.

**33. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein 4,646,722 in view of Vescovo, Jr. (herein Vescovo) 4,972,825 further in view of Darras 4,886,049.**

34. Silverstein in view of Vescovo discloses the invention as discussed above.

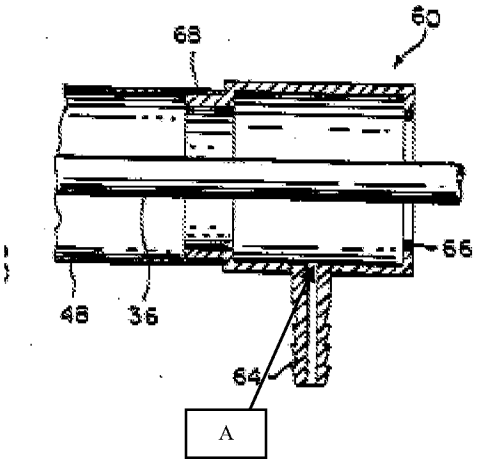
35. However, Silverstein in view of Vescovo fails to disclose a tear thread connected to said cover at said distal end and running parallel to said endoscope on the inside of said cover.

36. Darras discloses a tear thread 20 attached to an endoscope cover 10 (col. 3, lines 1-20) and running parallel to said endoscope on an inside of the cover 10, resulting in an improved

removing means for an endoscope cover which simplifies the cleaning and sterilization of endoscopes.

37. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the device of Silverstein in view of Vescovo with the structure of the tear thread 20 as taught by Darras in order to have provided an improved removing means for the endoscope cover which simplifies the cleaning and sterilization of the endoscope to prevent the potential spread of viruses from one patient to another due to ineffective cleaning and sterilization of such instruments.

**Inserted image 1: Fig. 6 from Silverstein 4,646,722**




***Conclusion***

38. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALIREZA NIA whose telephone number is (571)270-3076. The examiner can normally be reached on Mo.-Fri.-7:30 AM-5:00 PM EST-Alternate Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas J. Sweet can be reached on 571-272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Linda C Dvorak/
Supervisory Patent Examiner, Art Unit 3739

/A. N./
Examiner, Art Unit 3779
Alireza Nia
December 2nd, 2010